Postoperative Management of Zygomatic Arch Fractures: In-House Rapid Prototyping System for the Manufacture of Protective Facial Shields

Giovanni Dell'Aversana Orabona, MD, PhD, Vincenzo Abbate, MD,* Fabio Maglitto, MD,* Umberto Committeri, MD,* Giovanni Improta, PhD,§ Paola Bonavolontà, MD,* Alfonso Reccia, MD,* Teresa Somma, MD,† Giorgio Iaconetta, MD, PhD,‡ and Luigi Califano, MD, PhD**

Abstract: Zygomatic fractures account for 10% to 15% of all facial fractures. The surgical management of isolated zygomatic arch fractures usually requires open reduction treatment without fixation through an intraoral access. Therefore, the main problem in the nonfixed treatment of zygomatic arch fractures is related to the difficulty in obtaining a stable reduction for a period long enough to guarantee the physiological bone healing process. We propose an innovative "in-house" rapid prototyping (RP) protocol for the 3D-zygoma mask manufacture of a patient-specific protective device to apply after zygomatic arch fracture reduction. Our study includes 16 consecutive patients who underwent surgical open reduction for an isolated zygoma fracture without fixation between January 2017 and February 2018. The patients received regular postoperative checks at weeks 1 and 2. Before the device was removed, a multiple choice questionnaire was administered to measure the degree of wearability of the mask. The estimated cost of the production is around €5 per case and the construction time is around 90 minutes. Based on the encouraging results, obtained in our experience, we hope that other studies can be conducted to confirm our procedure and improve its functionality in the field of facial trauma.

Key Words: Arch fracture, CAD-CAM, in house, rapid prototyping, zygoma fracture

(*J Craniofac Surg* 2019;30: 2057–2060)

From the *Department of Neurosciences, Reproductive and Odontostomatological Sciences, Maxillofacial Surgery Unit; †Department of Neurosciences, Reproductive and Odontostomatological Sciences, Neurosurgery Unit, University of Naples "Federico II," Naples; ‡Neurosurgery Department, University of Salerno; and §Department of Public Health, University of Naples "Federico II," Naples, Italy.

Received October 8, 2019.
Accepted for publication October 11, 2019.

Address correspondence and reprint requests to Vincenzo Abbate, MD, Department of Neuroscience and Reproductive and Odontostomatological Sciences, Maxillofacial Surgery, School of Medicine, University of Naples "Federico II," Via Sergio Pansini 5, Naples 80131, Italy; E-mail: vincenzo.abbate@unina.it

Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jcraniofacialsurgery.com).

The authors report no conflicts of interest.

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000005930

Zygomatic fractures account for 10% to 15% of all facial fractures. These fractures commonly involve facial deformity and dysfunction, mainly consisting in zygomatic-facial collapse, zygomatic arch depression, outward arch rise, limited mouth opening, and numbness of the upper lip owing to infraorbital nerve injury.[1]

Commonly, zygomatic fractures affect adjacent bones such as the maxilla, nose, and orbital walls and therefore we generally talk about zygomatic complex fractures. An isolated involvement of the arch occurs in only about 14% of cases.[2] The surgical management of isolated zygomatic arch fractures usually requires open reduction treatment without fixation, as described by Gillies and Keen.[3] For complex comminuted fractures or huge cutaneous depressions, an open reduction with internal fixation, may be considered through a coronal approach.[4]

Therefore, the main problem in the nonfixed treatment of zygomatic arch fractures is related to the difficulty in obtaining a stable reduction for a period long enough to guarantee the physiological bone healing process. Several authors emphasize the role of external protection devices. These devices, worn directly on the patient's face, protect the bone heads to ensure a correct bone healing after open reduction without fixation.[5,6]

The main drawbacks of this technology are the high cost and long duration of the prototyping process. For these reasons, nowadays, these devices are reserved for cases of trauma in professional sportspeople, who require a quick recovery time. On this basis, the aim of our study is to demonstrate the reliability and effectiveness of an "in-house" rapid prototyping (RP) protocol for the manufacture of a 3D-zygoma mask as a protective device to apply after a nonfixed zygomatic arch fracture reduction. The shield obtained is customized for each patient to ensure a perfect fitting and the comfort required during the healing period.

MATERIALS AND METHODS

Our study included 16 consecutive patients who underwent surgical open reduction for an isolated zygomatic fracture without fixation between January 2017 and February 2018. All the patients were informed about the procedure and signed a preoperative consent for data recording in our clinical data base. All the patients underwent preoperative computer tomography (CT) scans as diagnostic tools (Fig. 1).

Preoperative Workflow

Skin Surface Segmentation and Mirroring

DICOM files, obtained from the CT scans, were processed in the InVesalius software (Technology of Information Renato Archer Center of the Ministry of Science and Technology, Campinas, Brazil) to produce a Standard Triangulation Language (STL) file of the patient's skin surface (Fig. 2).

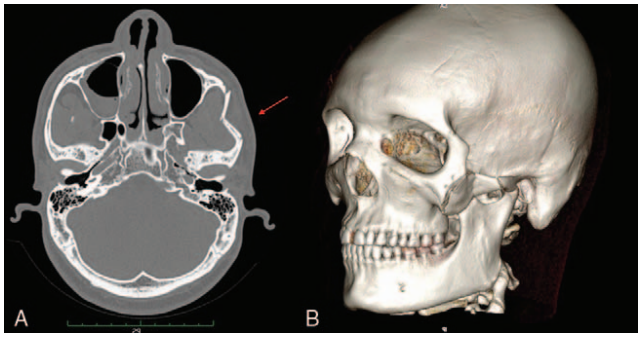

FIGURE 1. Computed tomography scan showing right zygomatic arch fracture: (A) axial view (red arrow shows the site of fracture); (B) 3D volume rendering.

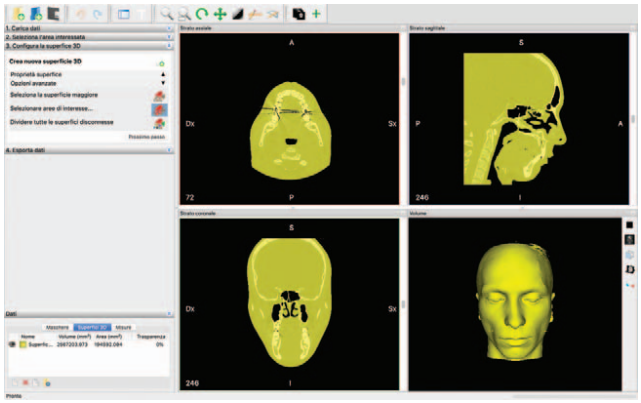

FIGURE 2. Skin surface segmentation through InVesalius open source software. Screenshots showing the patient skin segmentation procedure from DICOM data to STL files.

Meshmixer Processing

The STL file was uploaded in the open source software Meshmixer (Autodesk, San Rafael, CA). Through the "mirroring" tool, we used the contralateral zygomatic surface as a reference to develop the shield (Fig. 3A). The "brush tool" was used to virtually design the mask on the patient's skin (Fig. 3B). Then, through

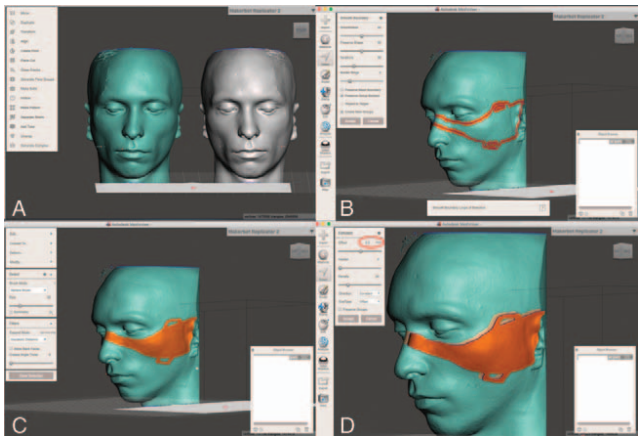

FIGURE 3. Meshmixer processing: (A) patient's skin surface mirroring; (B) virtual mask design on the patient s'skin surface using "brush tool;" (C) slots and anchors in the nasal and auricular region planning to ensure adeguate supports; (D) shield volume creation through the "extrusion tool" settled on 2.5 mm thickness (red circle).

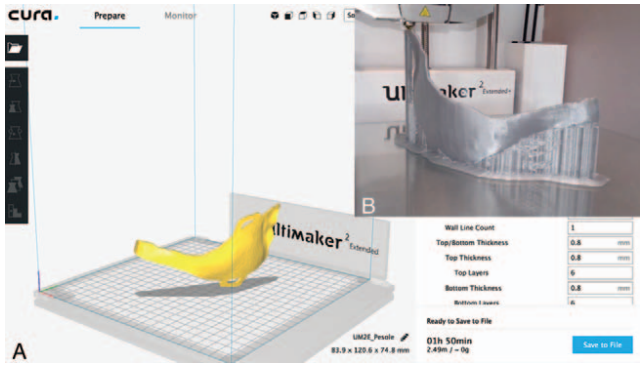

FIGURE 4. Slicing process: STL files have been imported into CURA open source software and optimized for Ultimaker 2 extended 3D Printer.

the "extrusion tool," we created the shield volume and settled the thickness at 2.5 mm (Fig. 3D). To ensure an adequate device support, we planned 2 slots in the superior and inferior edges and 2 anchors in the nasal and auricular region (Fig. 3C). This volume was then exported as an STL file.

Rapid Prototyping

The virtual mask was then imported into the CURA 2.6.1 (Ultimaker, Utrecht, Netherlands) open source software and optimized for an Ultimaker 2 extended 3D printer. A 0.6-mm nozzle extruder for the Bioflex medical polylactic acid (PLA) filament (ISO 10993-5:2009) was set (Fig. 4).

Postoperative Workflow

All the patients underwent open reduction treatment without fixation through an intraoral access. Immediately after treatment all the patients wore the customized shield for 14 days. Before the hospital discharge, they underwent a postoperative CT scan to assess the fracture reduction and the mask fitting (Fig. 5A–C) as a routine protocol according to our hospital health management. The patients received regular post-operative checks at weeks 1 and 2. Before the device was removed, a multiple choice questionnaire was administered to assess the degree of wearability of the mask.

FIGURE 5. Facial protective shields wearability and fitting on patient's skin: (A) patient sub-nasal view; (B) right arch fracture reduction and optimal shield fitting on postoperative computed to scan (red arrow); (C) patient lateral view.

The questionnaire consisted of 3 questions (items) and was built and evaluated according to a 5-point Likert scale. The 3 items of the questionnaire aimed at investigating 3 aspects of the mask wearability, that is:

1. the impact of the mask on the quality of life;
2. the impact of the mask on comfort;
3. the impact of the mask on the quality of sleep

For each question, the patient could give a score from 1 to 5 corresponding to the degree of tolerability of the mask (Supplemental Digital Content, Table 1, http://links.lww.com/SCS/A846). A score ranging from 12 to 15 was considered very good, from 8 to 11 good, from 4 to 7 acceptable, and <5 poor.

The reliability of the questionnaire was evaluated by calculating the Cronbach alpha and the item–item and item–total correlations using the software SPSS Statistics 20 (IBM, Armonk, NY).

RESULTS

In our sample, 11 patients (68.8%) were male and 5 (31.2%) were female. Seven (43.8%) had reported trauma after a car accident, 4 (25%) after a sporting injury and 5 (31.5%) owing to an accidental fall. The average age was 46 (ranging from 23 to 62). No surgical complications were detected during outpatient checks. No other complications, such as abrasion or allergic reactions, directly associated with the positioning of the device were reported. The CT scan performed showed an excellent fitting of the device to the skin and the correct reduction of the fracture in all cases. The reliability of the administered questionnaire was confirmed by the Cronbach alpha being equal to 0.730 (Supplemental Digital Content, Table 2, http://links.lww.com/SCS/A846). This is also confirmed by a good item–item and item–total correlation, as all the values were >0.3 (Table 2).

The effect of the mask on the 3 items defined in the administered questionnaire is reported in Figure 6A and the overall effect of the mask is shown in Figure 6B.

The overall results from the administered questionnaire are reported in Supplemental Digital Content, Table 3, http://links.lww.com/SCS/A846. In particular, 56.3% (9 patients) reported a good outcome, giving a score between 8 and 11 (mean 9.78); 12.5% (2 patients) classified the device as very good, scoring between 13 and 15 (mean 13.5); and 25% (4 patients) reported an acceptable score ranging between 4 and 7 (mean 6.5). Only 1 case (6.2%) left the study because of the total intolerability of the shield. The total average score was 9.4 (Table 3).

Based on these results, the tolerability of the mask is reported in Figure 6C.

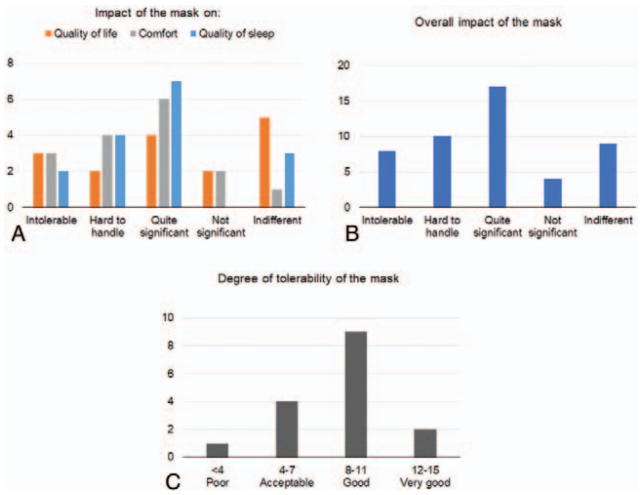

FIGURE 6. Results from the wearability questionnaire administered to the patients.

DISCUSSION

Owing to its prominent position in the facial skeleton, the zygomatic bone is more subject to traumas and fractures then other facial bones. It accounts for a significant portion of the orbital floor and the lateral wall of the orbit. The zygomatic arch, the malar eminence, represents a central structure in the facial morphology.[2,7]

An isolated fracture of the zygomatic arch may occur in about 14% of cases. These fractures are caused by fighting in 29.1%, traffic accidents in 21.5%, sports injuries in 15.8%, accidental falls in 14%, domestic accidents in 8.8%, and work accidents in 5% of cases.[1]

When the involvement of the zygoma concerns only the arch the difficulty in obtaining a stable reduction after open treatment without fixation puts the patient at risk of misalignment or pseudarthrosis resulting in esthetic and functional sequelae.

As reported by Cascone et al[8] in 2008, the bone healing process consists in 3 different stages: an early inflammatory stage, a repair stage, and a late remodeling stage. The first stage involves the creation of granulation tissue under the mediation of the prostaglandins. In the second stage, we find the presence of a soft callus occurring for 4 to 6 weeks after the trauma. During this time, if stabilization is not achieved, a fibrous tissue may develop. The final stage, called "late remodeling," results in the complete restoration of the bone shape, as it had originally been. The time required to achieve a full strength restoration is approximately 3 to 6 months.[8]

According to Kalfas, the most critical period of bone healing is the first 1 to 2 weeks in which inflammation and revascularization occur. In this period, the inflammatory process stimulates the differentiation of the mesenchymal cells into osteoblasts and osteoclasts. At the end of the second week, the formation of a soft fibrous callus allows sufficient stability to guarantee protection for most common traumatic injuries at a low energy.[9]

The subjects most at risk are professional sports people, for whom a rapid recovery and rehabilitation is required in order that they may resume their activities.[10]

To meet these requirements, several authors have reported methods for the construction of protective masks to be applied to protect the zygoma in the bone consolidation healing. These methods generally have a very high cost and a long prototyping time, which makes them not applicable to the majority of patients.[5,7]

Nowadays, a solution can be offered by computer-aided surgery and CAD/CAM technology, which have become part of daily surgical practice. In maxillofacial traumatology, this technology is commonly applied to maximize esthetic and functional outcomes. The impact of CAD/CAM technology, especially RP technology, has been transforming clinical practice in craniomaxillofacial surgery.[11]

D'Urso et al[12] suggested that the combined use of 3D CT imaging and RP has improved craniofacial operative planning and diagnosis by 82.2% and 95.2%, respectively. Our protocol is based on a mask, customized on the patient's anatomy and mirroring the healthy structure, manufactured in a "home-made" way to reduce the cost and prototyping time. The postoperative CT evaluation in the patients treated in our study showed a perfect fitting of the shield on the facial skin.

The specific tripod design of the shield allows it to discharge any impact forces on areas distant from the zygoma. The shields were produced keeping a minimum thickness of 2.5 mm of Ultimaker PLA. The material technical data sheet indicates an impact strength of 30.8 KJ/m^2, reported in the Charpy Impact test, which corresponds to

an impact resistance about 6 times higher than the strength of a punch generated by a professional boxer (4800 ± 227 N m).[13] The estimated cost of the prototyping process is around €5 per case, and approximately 90 minutes are necessary for the virtual CAD design in each case. These characteristics make this method applicable to most surgical cases.

The main drawback can derive from the off-label use of the planning software. This software requires a variable long learning curve for the specific use. Moreover, the inflammatory process related to the reduction procedure may provide a variable state of edema which can interfere with the correct fitting of the mask. It is therefore necessary to cause as little injury as possible during the fracture reduction.

In conclusion, based on the encouraging results obtained in our experience, we hope that other studies can be conducted to confirm our procedure and improve its functionality in the field of facial trauma.

REFERENCES

1. Ungari C, Filiaci F, Riccardi E, et al. Etiology and incidence of zygomatic fracture: a retrospective study related to a series of 642 patients. *Eur Rev Med Pharmacol Sci* 2012;16:1559–1562
2. Hussain K, Wijetunge DB, Grubnic S, et al. A comprehensive analysis of craniofacial trauma. *J Trauma* 1994;36:34–47
3. Yamamoto K, Murakami K, Sugiura T. Clinical analysis of isolated zygomatic arch fractures. *J Oral Maxillofac Surg* 2007;65:457–461
4. Hollier LH, Thornton J, Pazmino P, et al. The management of orbitozygomatic fracture. *Plast Reconstr Surg* 2003;111:2386–2392
5. Heise M, Eufinger H, Rarreck T. Individualized facial protection after fracture Management of the nasal bone and zygomatic arch in professional soccer players. *Mund Kiefer Gesichtschir* 2001;5:320–322
6. Procacci P, Ferrari F, Bettini G, et al. Soccer-related facial fractures: postoperative management with facial protective shields. *J Craniofac Surg* 2009;20:15–20
7. Obuekwe O, Owotade F, Osaiyuwu O. Etiology and pattern of zygomatic complex fractures: retrospective study. *J Natl Med Assoc* 2005;97:992–996
8. Cascone P, Petrucci B, Ramieri V, et al. Security Hi-tech Individual Extra-light Device Mask: a new protection for [soccer] players. *J Craniofac Surg* 2008;19:772–776
9. Kalfas IH. Principles of bone healing. *Neurosurg Focus* 2001;15:E1
10. Cerulli G, Carboni A, Mercurio A. Soccer-related cranio-maxillofacial injuries. *J Craniofac Surg* 2002;13:627–630
11. Dell'Aversana Orabona G, Abbate V, Maglitto F, et al. Low-cost, self-made CAD/CAM-guiding system for mandibular reconstruction. *Surg Oncol* 2018;27:200–207
12. D'Urso PS, Barker TM, Earwaker WJ, et al. Stereolithographic biomodelling in cranio-maxillofacial surgery: a prospective trial. *J Craniomaxillofac Surg* 1999;27:30–37
13. Buśko K, Staniak Z, Szark-Eckardt M, et al. Measuring the force of punches and kicks among combat sport athletes using a modified punching bag with an embedded accelerometer. *Acta Bioeng Biomech* 2016;18:47–54